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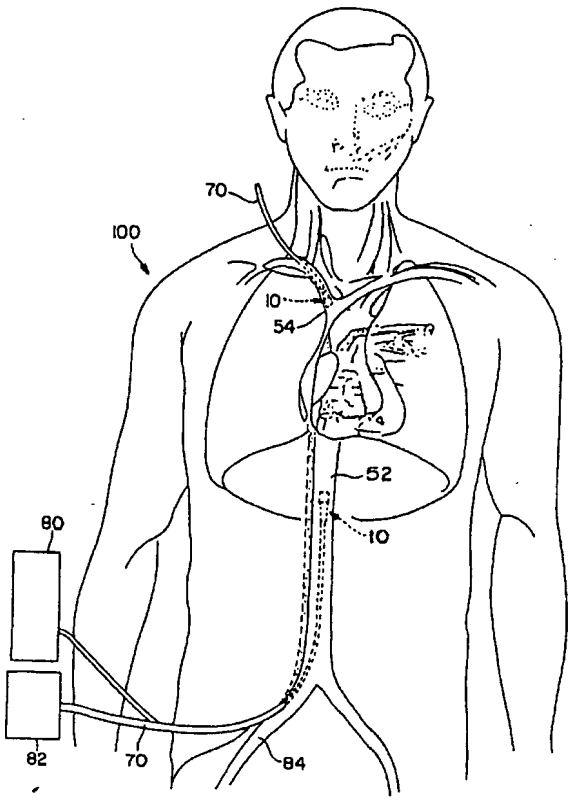
(54) Title: ACTIVE INTRAVASCULAR LUNG

(57) Abstract

An active intravascular lung (10) includes a gas exchanger (14) for delivering oxygen to blood flowing across the gas exchanger (14) when positioned within the cavity (52, 54) and a pump (16) in proximity to the gas exchanger (14) for creating a differential blood pressure across the gas exchanger (14). When the gas exchanger (14) is positioned percutaneously in the blood flow cavity (52, 54), oxygen can be delivered to the blood independent of the operation of the patient's heart.



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ACTIVE INTRAVASCULAR LUNG

Field of the Invention

The present invention relates generally to artificial lungs and, more particularly, to an active fluid flow intravascular lung for use in patients with both heart and lung ailments.

Description of the Related Art

Prior art lung assist devices have attempted to supply oxygen and remove carbon dioxide from patients suffering from acute illnesses such as pneumonitis, atelectasis, various heart and circulatory ailments, fluid in the lungs, obstruction of pulmonary ventilation, or lung injury caused by heat, noxious gases, or other factors. Prior techniques for assisting the lungs under these conditions have included, among others, the use of intravascular lung assist devices. With these types of devices, there is no need for anticoagulants, lung resection or constant supervision by teams of specialized technicians, as in heart-lung machines. The skin and circulation need only be violated at one site, which may lessen the risk of infection.

Despite their advantages, intravascular lung assist devices typically have a relatively poor oxygen transfer rate to the blood, which is below the ideal rate, due to convection, diffusion, blood flow rate across the intravascular lung, and oxygen saturation of the input blood. Even if the convective and diffusive limitations were eliminated, the maximum oxygen transfer would still be limited by the blood flow rate and the oxygen saturation of the input blood. A patient's blood flow rate is determined solely by how well the heart functions. When a patient suffers from both heart and lung ailments, the problem of sufficient oxygen transfer to the blood from intravascular lung assist devices is further augmented. Prior art intravascular lungs are passive and depend solely upon the blood flow rate generated by the patient.

SUMMARY OF THE INVENTION

These and other problems of the prior art are overcome by the provision of an active intravascular lung assist device configured for percutaneous venous insertion into a patient. According to one aspect of the invention, the device includes a gas exchanger for delivering oxygen to blood flowing across the gas exchanger when positioned within the cavity and a pump in proximity to the gas exchanger for creating a differential blood pressure across the gas exchanger. Thus, when the gas exchanger is positioned in the blood flow cavity, oxygen can be delivered to the blood independent of the operation of the patient's heart.

According to a further aspect of the invention, a catheter extends between the gas exchanger and the pump to control the direction, velocity, and pressure of blood flow through the gas exchanger. In another aspect, the pump is driven by a flexible drive cable that is adapted to extend and be driven extracorporeally when the pump and gas exchanger are positioned in the blood flow cavity.

In one embodiment, the pump is located at a distal end of the device and is inserted into the cavity ahead of the gas exchanger to pull blood through the gas exchanger. The flexible drive cable extends through the gas exchanger and catheter to drive the pump.

In a second embodiment, the gas exchanger is located at a distal end of the device and is inserted into the cavity ahead of the pump, so that blood is pushed through the gas exchanger.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described with reference to the drawings in which:

FIG. 1 is a schematic view of an active intravascular lung assist device positioned within a vein according to a first embodiment of the invention;

FIG. 2 is a schematic view of an active intravascular lung assist device positioned withing a vein according to a second embodiment of the invention;

FIG. 3 is a top view of a patient having an active intravascular lung assist device placed in the inferior and superior vena cavae;

FIG. 4 is a partially broken away side view of a blood pump according to the present invention; and

FIG. 5 is a perspective view of a catheter for use with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIG. 1, an active intravascular lung assist device 10 according to the present invention is positioned within a patient's vein 12. The device 10 preferably includes an intravascular membrane lung 14 connected to an active blood pump 16 via a catheter 18. The structure of the membrane lung is conventional such as that disclosed in U.S. Patent No. 5,336,164 to Snider et al., the disclosure of which is hereby incorporated by reference. In the membrane lung shown in the Snider et al. patent, a large number of microporous fibers are tethered at one end to a manifold sleeve. The fibers are in communication with the lumina of a catheter to transfer oxygen to the blood and remove carbon dioxide therefrom. One or a plurality of such manifold sleeves may be incorporated into the active intravascular device 10 of the present invention.

Referring now to FIG. 4, a miniature high-speed intravascular single stage blood pump 16 is shown. The pump comprises an outer housing 32 having a rotor 34 rotatably mounted at one end thereof and a stator 44 fixedly mounted at the other end thereof. A journal bearing 46 separates the stator 44 and rotor 34.

Blood enters the pump 16, in the direction of arrow 26, by passing around rotor 34 at the pump inlet end 28 provided at one end of an outer housing 32. The blood is rotated by the rotor 34 and forced through the housing 32, past the fixed stator 44, and ultimately, is exhausted at the pump outlet end 30 provided at the other end of the housing 32. In the embodiment shown in FIG. 4, the rotor 34

is provided with two rows of blades 36, 38. In the preferred embodiment, only a single row of blades 36 is provided on the rotor 34. Each row preferably consists of three blades spaced 120 degrees apart which wrap helically around at least a portion of the rotor body. The helical orientation of the first row of blades 36 produce a component of axial acceleration of the blood from the left to the right as shown in FIG. 4. The trailing edge of the second row of blades 38 is slightly S-shaped to form a negative angle 40 at the base of the trailing edge adjacent the rotor 34 and a positive angle 43 at the tip of the trailing edge spaced furthest away from the rotor 34. The blades 38 also have a high leading edge twist 42. This arrangement maintains a uniform velocity of the blood flow along the trailing edge of each blade 38 in order to prevent any turbulence which might cause hemolysis or separation and causes the blood to flow only along an axial component of acceleration. It also provides an increased pressure rise necessary for enabling this stage to meet its operating criteria. The high twist is necessary to overcome the viscous losses in the low Reynolds range in which blood pumps of this size operate.

The stator 44 of the pump 16 includes a journal bearing 46, and a bearing block 48. Three reverse-twisted blades 50 provided on the stator 44 and are substantially longer than the rotor blades 36 and 38. The stator blades 50 form the support for the housing 32 spacing the housing from the stator and rotor bodies.

Referring again to FIG. 1, the pump 16 is driven by a cable 20 encased in a sheath 22 that preferably has an outer layer formed of a soft, blood compatible material and an inner layer formed of a stiff, abrasion-resistant material. The stiff inner layer faces the cable 20 that drives the pump 16. Operation of this type of pump is described in greater detail in U.S. Patent No. 4,846,152 to Wampler et al., the disclosure of which is hereby incorporated by reference. The pump 16 may be mounted upstream from the membrane lung 14 as shown in FIG. 1 or may be mounted downstream from the membrane lung 14 as shown in FIG. 2. In the case of FIG. 2, the sheath 22 and cable 20 extend through membrane lung 14 and catheter 18 to pump 16. The outer sheath layer is in direct contact with the blood and therefore must be formed of the blood compatible material. Although a

single stage pump is preferred due to its relatively smaller size, expense, and reduction of hemolysis, dual stage blood pumps may also be used.

Referring now to FIG. 3, the active intravascular lung assembly 10 shown in dashed line is preferably positioned within the inferior vena cava 52 of a patient 100. An oxygenator 80 for membrane lung 14 and drive mechanism 82 for blood pump 16 are provided at the proximal end of a catheter 70. A suitable drive mechanism for powering intravascular blood pumps is disclosed in U.S. Patent No. 4,895,557 to Moise et al., the disclosure of which is hereby incorporated by reference.

Turning now to FIG. 5, a commercially available diagnostic pulmonary artery catheter 70 such as the OPTICATH™ catheter manufactured and sold by Oximetrix, Inc. of Mountain View, California is illustrated. This catheter 70 is formed of a flexible plastic material, preferably extruded polyvinyl chloride. Specifically, it is formed to include a ventilation, or gas inlet conduit 72, a ventilation or gas outlet conduit 74, a blood sampling conduit 76, and a cable drive conduit 78. The catheter 70 may be of any suitable length and size appropriate to accommodate the gas exchange requirements of the patient.

The active intravascular lung assist device 10 of the present invention is intended to be inserted and removed percutaneously without the need for surgery. The device 10 can be positioned in the inferior vena cava 52 via the femoral vein 84 or iliac vein, preferably by the well-known Seldinger technique as described in U.S. Patent No. 5,487,727 referenced above. Alternatively, the device 10 can be inserted into the superior vena cava 54 through the jugular vein or brachial vein. In still another embodiment, one intravascular lung device 10 can be positioned in the superior and one in the inferior vena cava depending upon the oxygenating needs of the patient.

In use, the intravascular lung assist device 10 is positioned within a vein carrying oxygen depleted blood such as the vena cava and the pump is operated to create a pressure differential across the intravascular lung from 1 to 100 mm Hg depending on the patient's needs. Ideally, the pump will operate within a pressure

differential range of 20-40 mm Hg, and preferably at a pressure differential of 30 mm Hg. At least a portion of the blood flowing through the vein is drawn through the pump and oxygenator, thereby enhancing the effectiveness of the oxygenator in exchanging carbon dioxide for oxygen.

With the present arrangement, the maximum oxygen transfer to the blood is no longer limited by the blood flow rate generated solely by the patient as in prior art devices. Actively forcing the oxygen depleted blood through the oxygenator enhances the performance of the oxygenator so that a greater population of patients can utilize the intravascular lung technology. For example, patients who suffer from both lung ailments and who have reduced blood flow as a result of heart problems can utilize this system.

Reasonable variation and modification are possible within the spirit of the foregoing specification and drawings without departing from the scope of the invention.

CLAIMS

The embodiments for which an exclusive property or privilege is claimed are defined as follows:

1. An active intravascular lung assist device configured for insertion into a cavity of a patient through which blood flows, said device comprising:

a gas exchanger adapted to deliver oxygen to blood flowing across the gas exchanger when positioned within the cavity; and

a pump positioned adjacent the gas exchanger for creating a differential blood pressure across the gas exchanger thereby forcing blood through the exchanger;

whereby the gas exchanger when positioned in the cavity can deliver oxygen to the blood independent of blood fluid flow generated by the patient's heart.

2. An active intravascular lung assist device according to claim 1 and further comprising a catheter fluidly interconnecting the gas exchanger and the pump.

3. An active intravascular lung assist device according to claim 2 wherein the pump is driven by a flexible drive cable that is adapted to extend extracorporeally when the pump and gas exchanger are positioned in the cavity.

4. An active intravascular lung assist device according to claim 3 wherein the cable extends through the gas exchanger and catheter to the pump.

5. An active intravascular lung assist device according to claim 1 wherein the gas exchanger has an inlet and an outlet, and the pump has an inlet and an outlet, the inlet of the pump being positioned adjacent the outlet of the gas exchanger so that the pump draws the blood through the exchanger.

6. An active intravascular lung assist device according to claim 5 and further comprising a catheter fluidly interconnecting the gas exchanger and the pump.

7. An active intravascular lung assist device according to claim 5 wherein the pump is driven by a flexible drive cable that is adapted to extend extracorporeally when the pump and gas exchanger are positioned in the cavity.

8. An active intravascular lung assist device according to claim 7 wherein the cable extends through the gas exchanger to the pump.

9. An active intravascular lung assist device according to claim 1 wherein the gas exchanger has an inlet and an outlet, and the pump has an inlet and an outlet, the outlet of the pump being positioned adjacent the inlet of the gas exchanger so that the pump pushes the blood through the exchanger.

10. An active intravascular lung assist device according to claim 9 and further comprising a catheter fluidly interconnecting the gas exchanger and the pump.

11. An active intravascular lung assist device according to claim 1 wherein the pump is driven by a flexible drive cable that is adapted to extend extracorporeally when the pump and gas exchanger are positioned in the cavity.

12. An active intravascular lung assist device according to claim 11 and further comprising a multi-lumen catheter having a proximal end mounted to the gas exchanger and a distal end mounted to a source of a first gas, the multi-lumen catheter being adapted to fluidly conduct a first gas therethrough in a first lumen, a second gas therethrough in a second lumen, and also adapted to receive therein at least a portion of the drive cable.

13. A method of oxygenating blood comprising the steps of:

providing a gas exchanger adapted to exchange oxygen for carbon dioxide as blood passes across the gas exchanger;

roviding a pump which is fluidly interconnected to the gas exchanger;

percutaneously positioning the gas exchanger and pump within a blood flow conduit within a patient;

supplying oxygen to the gas exchanger; and

driving the pump to force blood to flow across the gas exchanger.

14. A method of oxygenating blood according to claim 13 wherein the pump is positioned upstream from the gas exchanger so that the pump pushes blood through the gas exchanger.

15. A method of oxygenating blood according to claim 13 wherein the pump is positioned downstream from the gas exchanger so that the pump draws blood through the gas exchanger.

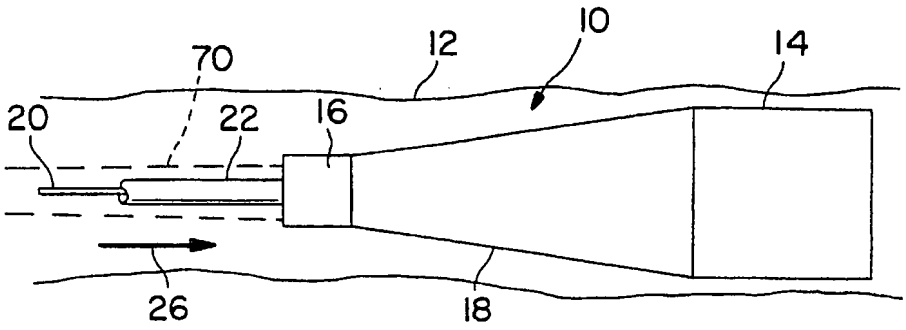

FIG. 1

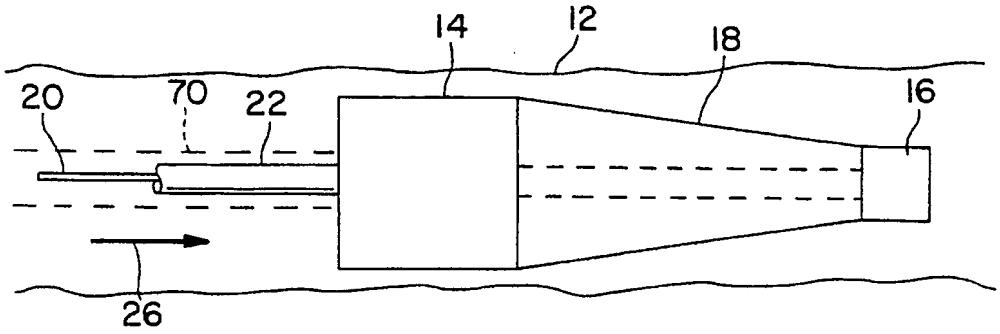

FIG. 2

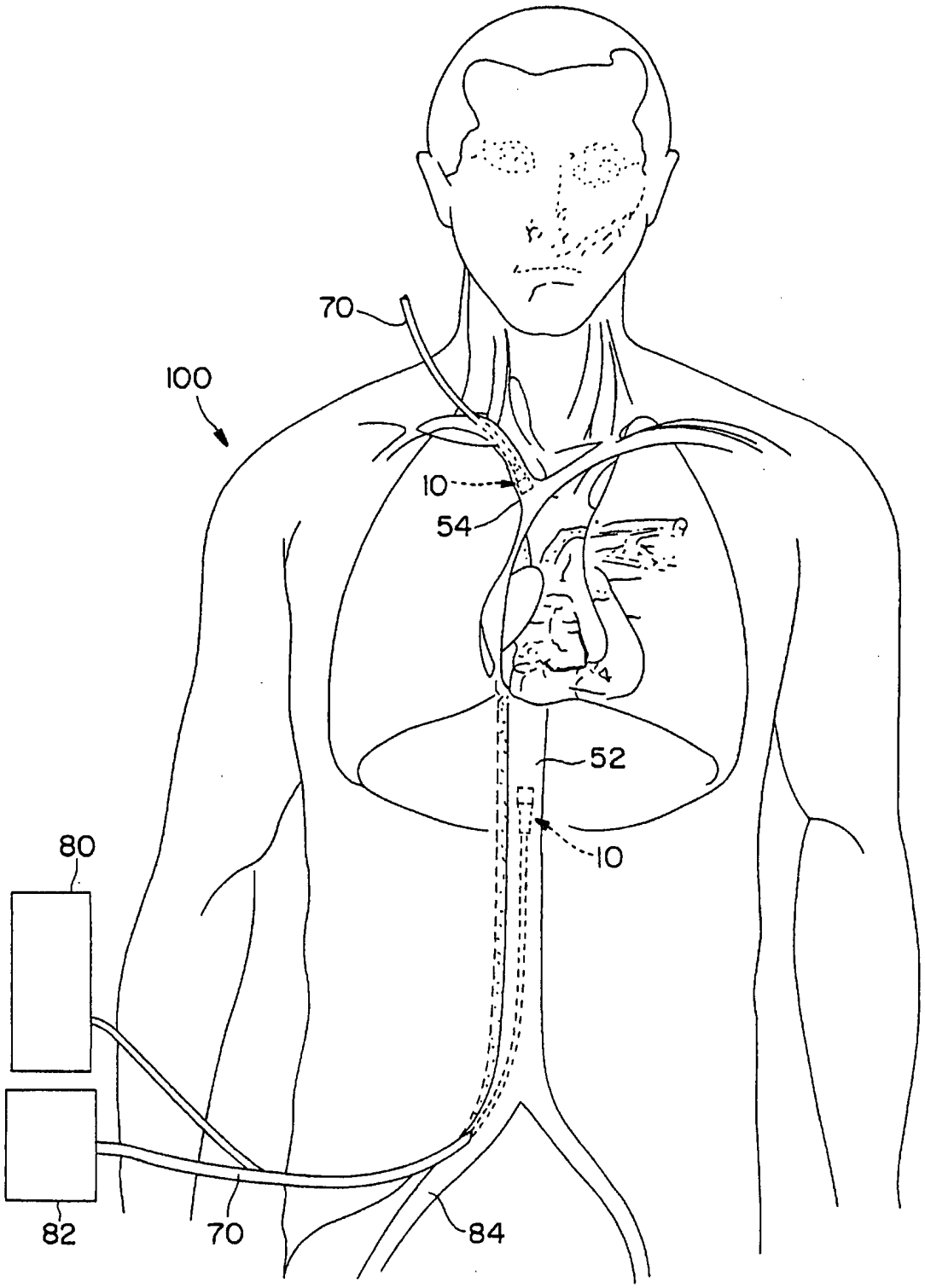

FIG. 3

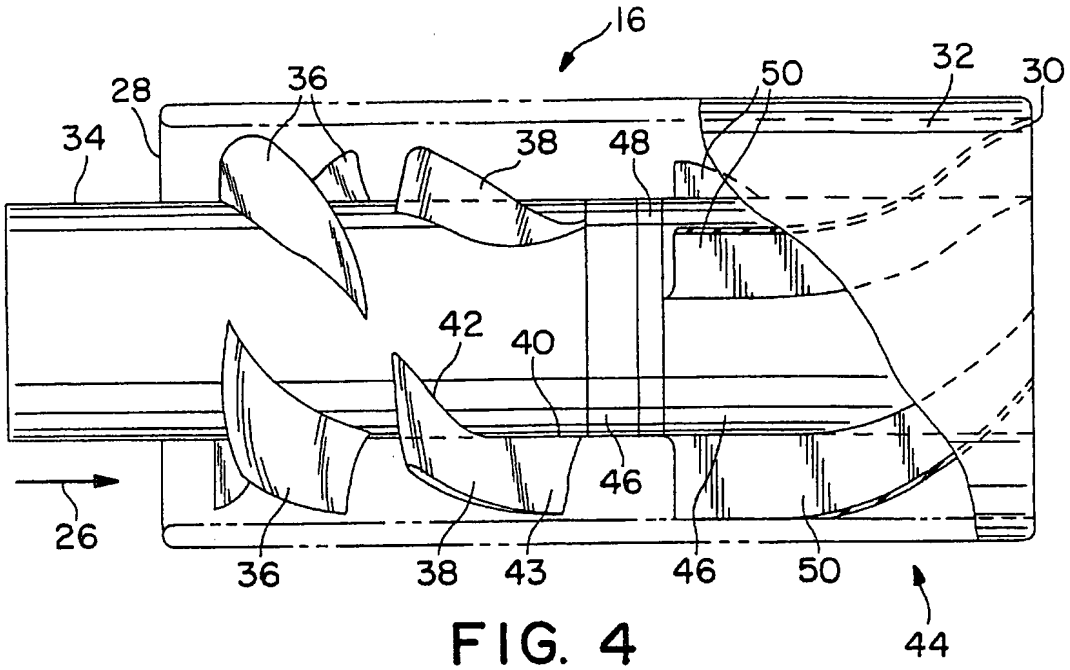
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FIG. 4

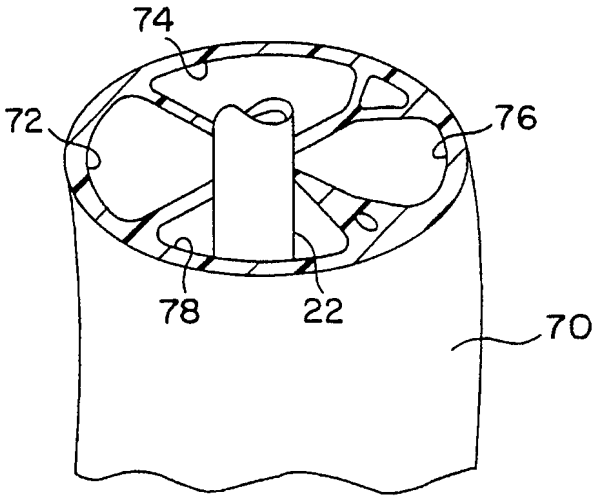
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FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/01906

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M1/16 A61M1/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 697 221 A (PRESIDENT OF HIROSHIMA UNIVERS) 21 February 1996 see abstract; figure 1 see column 2, line 42 - column 4, line 38 ---	1
A	US 5 308 314 A (FUKUI YASUHIRO ET AL) 3 May 1994 see abstract; figures 1-4 see column 2, line 42 - line 69 ---	1
A	EP 0 569 319 A (HATTLER BRACK G) 10 November 1993 see abstract; figures 1-5 see page 4, line 33 - page 5, line 12 --- -/--	1

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
14 July 1997	25.07.97

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/01906

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 92 17118 A (SHTURMAN CARDIOLOGY SYSTEMS IN) 15 October 1992 see abstract; figures 27A-30 see page 22, line 15 - page 23, line 11 -----	1

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/01906

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-15
because they relate to subject matter not required to be searched by this Authority, namely:
Please see Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 97/01906

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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